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08/470,421

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/470,421	06/06/95	CORBOLD	S 1768-128

18M1/1210

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EXAMINER	
GAMBEL, P	
ART UNIT	**PAPER NUMBER**
1806	11

DATE MAILED: 12/10/96

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☑ Responsive to communication(s) filed on 9/5/96, 10/5/96

☑ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☑ Claim(s) 33-44 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☑ Claim(s) 33-44 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892

☑ Information Disclosure Statement(s), PTO-1449, Paper No(s). 10

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

– SEE OFFICE ACTION ON THE FOLLOWING PAGES –

DETAILED ACTION

1. The Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1806.

2. Applicant's amendment, filed 9/26/96 (Paper No. 6) is acknowledged.
Claims 1-5 and 8-17 are canceled.
Claims 18-32 are added.

Applicant's amendment, filed 12/5/96 (Paper No. 10) is acknowledged.
Claims 18-32 are canceled.
Claims 33-44 are added.

Claims 6-7 have been cancelled.
Claims 33-44 are pending and being acted upon.

3. The text of those sections of Title 35 USC not included in this Action can be found in a prior Office Action.

This Action will be in response to applicant's arguments, filed 9/26/96 (Paper No. 6).
The rejections of record can be found in the previous Office Action (Paper No. 5).

4. Claims 33-44 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 34, 36-45 of copending application Serial No. 08/289,532. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn essentially to the same use of CD4- and/or CD8-specific antibodies in the generation of immunological tolerance.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant requested that this be held in abeyance upon the indication of allowable subject matter.

5. Upon reconsideration of the art in view of applicant's amended claims, filed 12/5/96 (Paper No. 10) and arguments in conjunction with the Crowe/Johnston declarations under 37 C.F.R. § 1.132, filed 9/26/6 (Paper No. 6); the previous rejections under 35 U.S.C. § 112, first paragraph, as they would apply to the instant claims are obviated.

6. The previous rejection of claims under 35 U.S.C. § 112, second paragraph, have been obviated by applicant's amendment, filed 12/5/96 (Paper No. 10).

7. The previous rejections of claims drawn to antibody compositions under 35 U.S.C. § 102(b) as being clearly anticipated by Waldmann. (Ann. Rev. Immunol.) and Qin et al. (J. Exp. Med.have been obviated by the cancellation of said antibody composition claims. ,

8. Claims 33-44 are rejected under 35 U.S.C. § 103 as being unpatentable over Qin et al. (J. Exp. Med., 1989; 1449, #AS) in view of Waldmann (Ann. Rev. Immunol., 1989; 1449, #AT), Waldmann (Am. J. Kid. Dis., 1988; 892, of record) and Cateron et al. (J. Immunol., 1988; 1449, AR) for the reasons of record as set forth in the previous Office Action (Paper No. 5).

Applicant's arguments in conjunction with the Crowe/Johnston declarations under 37 C.F.R. § 1.132, filed 9/26/6 (Paper No. 6) have been fully considered but are not found convincing. Applicant argues that the prior art relied upon chimerism resulting from bone marrow transplantation to induce tolerance or unresponsiveness and that the prior art simply required the antibody therapy as an immunosuppressant regimen. In contrast, applicant argues that the instant methods "consists essentially of" antibody treatment. However, applicant's claims are broadly written on inducing long term immunological unresponsiveness to specific antigens, wherein said specific antigens are transplantation antigens provided by bone marrow grafts. Therefore, applicant's reliance on antibody therapy alone runs contrary to applicant's claimed methods. Tolerance or long term unresponsiveness induction was known to rely upon the presence of antigen at the time the invention was made. Also, it is noted that applicant's arguments rely in part on the use of whole antibodies rather than antibody fragments. Therefore, applicant's arguments are not commensurate in scope of the claimed methods which rely on non-depleting antibody fragments as well as whole antibodies.

Applicant's arguments are not found persuasive and the rejection is maintained on the claims as they are currently written.

9. It appears that the Waldmann declaration under 37 C.F.R. § 1.131, filed 9/26/6 (Paper No. 6) is meant to serve as a Katz-type declaration under 37 C.F.R. § 1.132 over previous rejections under 35 U.S.C. § 102(f). However, no such 35 U.S.C. § 102(f) rejection is outstanding in the instant application and the references cited (i.e. Qin, Eur. J. Immunol., 1990 and Cobbold et al., Eur. J. Immunol., 1990) are not applied in the prior art rejections of the instant application.

10. No claim is allowed.

11. Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL.** See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

12. This application is subject to the provisions of Public Law 103-465, effective June 8, 1995. Accordingly, since this application has been pending for at least two years as of June 8, 1995, taking into account any reference to an earlier filed application under 35 U.S.C. 120, 121 or 365(c), applicant, under 37 CFR 1.129(a), is entitled to have a first submission entered and considered on the merits if, prior to abandonment, the submission and the fee set forth in 37 CFR 1.17(r) are filed prior to the filing of an appeal brief under 37 CFR 1.192. Upon the timely filing of a first submission and the appropriate fee of $375 for a small entity under 37 CFR 1.17(r), the finality of the previous Office action will be withdrawn. In view of 35 U.S.C. 132, no amendment considered as a result of payment of the fee set forth in 37 CFR 1.17(r) may introduce new matter into the disclosure of the application.

If applicant has filed multiple proposed amendments which, when entered, would conflict with one another, specific instructions for entry or non-entry of each such amendment should be provided upon payment of any fee under 37 CFR 1.17(r).

12. Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CMI Fax Center telephone number is (703) 308-4242 or (703) 305-7939.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee can be reached on (703) 308-2731. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1800 receptionist whose telephone number is (703) 308-0196.

Phillip Gambel
Patent Examiner
Group 1800
December 5, 1996

LILA FEISEE
SUPERVISORY PATENT EXAMINER
GROUP 1800